

§ 21.72

21 CFR Ch. I (4–1–09 Edition)

(e) Where an accounting is required under paragraph (d) of this section, the Food and Drug Administration shall:

(1) Record the name and address of the person or agency to whom the disclosure is made and the date, nature, and purpose of the disclosure. The accounting shall not be considered a Privacy Act Record System.

(2) Retain the accounting for 5 years or for the life of the record, whichever is longer, following the disclosure.

(3) Notify those recipients listed in the accounting of amendments or disputes concerning the records previously disclosed to them pursuant to § 21.51(d)(3), § 21.53(c), or § 21.54(c).

(4) Except when the record is exempt from individual access and contest under § 21.61 or to the extent that the accounting describes a transfer for a law enforcement purpose pursuant to paragraph (a)(7) of this section, make the accounting available to the individual to whom the record pertains, in accordance with procedures of subpart D of this part.

(f) A single accounting may be used to cover disclosure(s) that consist of a continuing dialogue between two agencies over a prolonged period, such as discussion of an enforcement action between the Food and Drug Administration and the Department of Justice. In such cases, a general notation may be made that, as of a certain date, contract was initiated, to continue until resolution of the matter.

[42 FR 15626, Mar. 22, 1977, as amended at 50 FR 52278, Dec. 23, 1985; 54 FR 9038, Mar. 3, 1989]

§ 21.72 Individual consent to disclosure of records to other persons.

(a) Individuals may consent to disclosure of records about themselves to other persons in several ways, for example:

(1) An individual may give consent at the time that the information is collected for disclosure for specific purposes or to specific persons.

(2) An individual may give consent for disclosure of his records to a specific person.

(3) An individual may request the Food and Drug Administration to transcribe a specific record for submission to another person.

(b) In each case the consent shall be in writing and shall specify the individual, organizational unit, or class of individuals or organizational units to whom the record may be disclosed, which record may be disclosed, and, if applicable, for what time period. A blanket consent to release all of an individual's records to unspecified individuals or organizational units will not be honored. Verification of the identity of the person to whom the record is to be disclosed shall be made in accordance with § 21.44. Consent documents shall be retained for a period of at least 2 years. If such documents are used as a means of accounting for the disclosure, they shall be retained as provided in § 21.71(e)(2).

§ 21.73 Accuracy, completeness, timeliness, and relevance of records disclosed from Privacy Act Record Systems.

(a) The Food and Drug Administration shall make reasonable efforts to assure that a record about an individual in a Privacy Act Record System is accurate, relevant to a Food and Drug Administration purpose, timely, and complete before such record is disclosed under § 21.71.

(b) Paragraph (a) of this section shall not apply to disclosures that are required under part 20 of this chapter (the public information regulations) or made to other Federal Government departments and agencies. Where appropriate, the letter disclosing the information shall indicate that the Food and Drug Administration has not reviewed the record to assure that it is accurate, relevant, timely, and complete.

§ 21.74 Providing notice that a record is disputed.

Whenever an individual has filed a statement of disagreement with the Food and Drug Administration concerning a refusal to amend a record under § 21.51(a)(2) or with another agency that provides the record to the Food and Drug Administration, the Food and Drug Administration shall in any subsequent disclosure under this subpart provide a copy of the statement of disagreement and a concise statement by